

Premarket Notification 510(k) - 510(k) Summary

AUG 24 2007

Tizian Ceramic

Tizian Ceramic is a glass ceramic material, colored to match the VITAPAN® color system. It is used for the ceramic coating of titanium and titanium alloys as well as zirconium dioxide-based frame materials. Tizian guarantees an easy and reliable treatment without the need for long-term cooling.

Opagues for titanium and titanium alloys are prepared as follows: No additional bonder is necessary, as the opaque's unique structural condition already acts as a seal for the titanium surface. A strong and reliable bond is created between the metal and the dental ceramics material. The opaque liquid is added to the opaque powder and mixed until the desired consistency is reached. A thin layer of opaquer is applied so that almost the entire surface is coated after the first opaque firing. Best results are achieved when coating approximately 70 % of the metal frame material. This optimum surface area must be reached by the end of the second opaque firing. After firing the opaque appears shiny.

The shoulder material is applied to the shoulders of the rough-textured material in a thin layer insulating it. The required shoulder material powder and liquid is mixed to the shoulder. It is riffled lightly until solid, excess liquid is extracted and the material is dried thoroughly.

A number of different liners for zirconium oxide frames ensures that the correct tooth colorant is already applied to the zirconium oxide frame during the first processing step. The liner is mixed with the modelling liquid to the desired consistency, then it is applied evenly onto the frame. If second liner firing is necessary, the above process must be repeated.

To ensure that the colorant stabilizes from within the material, it is recommended to apply opaque dentin in numerous layers to a smaller tooth form. The opaque dentin, dentin, incisal and transparent mixtures are mixed with modelling fluid to the desired consistency. Then, they are applied in small amounts to the cervical and interdental areas and vibrated lightly until solid. Next, the desired mixtures are applied in layers to the tooth surface. Once this has been done, the solidifying process is stopped and the material is cleaned carefully, removing any loose particles with a suction extractor. If further firings are required, the above process is repeated.

When using glazing materials or stains, they are mixed with the paint liquid to the desired consistency, then applied to the ceramic surface.

### Tizian Zr Blanks

Tizian Blanks are composed of tetragonal zirconium dioxide stabilized with yttrium oxide. They are available in different sizes and permit the production of ceramic crowns and bridges. The material is partially sintered and can be processed using copy milling as well as CAD/CAM procedures.

The blanks are suited to the production of primary conus and telescope crowns, crown and bridge works in front and side tooth areas, abutments and inlays.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Anke Puent  
Assistant  
Schütz-Dental GmbH  
Dieselstrasse 5-6  
Rosbach, Hessen,  
GERMANY 61191

AUG 24 2007

Re: K071010  
Trade/Device Name: Tizian Ceramic and Tizian Zr Blanks  
Regulation Number: 872.6660  
Regulation Name: Porcelain Powder for Clinical Use  
Regulatory Class: II  
Product Code: EIH  
Dated: August 1, 2007  
Received: August 3, 2007

Dear Ms. Puent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K071010

Device Name: Tizian

Indications for Use:

*Tizian Ceramic* is a glass ceramic material, colored to match the VITAPAN® color system. It is used for the ceramic coating of titanium and titanium alloys as well as zirconium dioxide-based frame materials.

*Tizian Zr Blanks* are produced of yttrium oxide-stabilized tetragonal zirconium dioxide in several different sizes for the production of full ceramic crowns, bridges and inlays.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

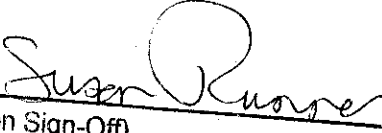
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices  
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